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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/263,689 03/05/99 NI

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EXAMINER

CANFIELD, K

ART UNIT	PAPER NUMBER
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1642

DATE MAILED:

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HM12/0911
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/263,689

Applicant(s)
Ni et al

Examiner
Karen Canella

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1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-27, 68-70, 77-80, 90-114, and 116-140 is/are pending in the application.
- 4a) Of the above, claim(s) 24-27, 68-70, and 77-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 90-114 and 116-140 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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Response to Amendment

1. Claim 115 has been canceled. Claims 114, 116 and 133 have been amended. Claims 24-27, 68-70 and 77-80 remain withdrawn from consideration. Claims 90-114 and 116-140 are under consideration.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections Withdrawn

3. The rejection of claims 114 and 119 under 35 U.S.C. 102(b) as being anticipated by Massa et al (Journal of Biological Chemistry, 1995, Vol. 270, pp. 5032-5038) as evidenced by Accession Number P47967 is withdrawn as applicant has amended the claims to recite longer fragments of SEQ ID NO:4.

Claim Rejections Maintained

4. The rejection of claims 90-114 and 116-140 under 35 U.S.C. 101, because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility, is maintained for reasons of record. Applicant argues that the instant galectin-9 would have an inherent utility based on being a member of the galectin family and having the ability to bind galactose. However, other members of the galectin family exhibit widely different function. For instance, galectin-1 is known to induce apoptosis in T-cells and T-cell leukemia, while galectin-3 is known to confer resistance to apoptosis in cultured cells. Given that the instant galectin-9 has the ability to bind galactose as galectins 1 and 3, there is no molecular evidence in the specification that this property can be related to induction or inhibition of apoptosis. Applicant further argues that the instant galectin-9 has a high degree of homology with ecalectin with the exception of twelve consecutive amino acids found in ecalectin and that ecalectin is an eosinophil chemoattractant. This has been considered but not found persuasive, as the instant specification makes no mention of the chemoattractant qualities of galectin-9. Applicant argues

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that the instant galectin-9 can be used to diagnose asthma in a human patient and sites page 25, line 22 to page 27, line 18 as support for this utility. However, this citation discusses only general properties of antigenic epitopes. Applicant argues that the specification on page 29, lines 5-7 provides support for the utility of galectin-9 in the diagnosing of Hodgkin's disease. The cited page and line numbers state that the instant galectin-9 is useful for detecting diseases such as asthma, allergic diseases, cancers including breast, ovary, prostate, bone, liver, lung, pancreas, spleen, melanoma, renal astrocytoma and Hodgkin's disease, . These utilities are not considered to be specific and substantial because the specification fails to disclose any particular function beyond the binding of galactose or the biological significance for the instant galectin-9 protein and therefore, as the functions of proteins in the galectin family range from inducing apoptosis, inhibiting apoptosis, and inducing chemoattraction, the function of the instant galectin-9 can not be predicted. Therefore in the absence of any further objective data, the utilities recited in the paragraph supra are prophetic.

5. The rejection of claims 1, 2, 13 and 25 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record.

6. In the event that Applicants might be able to overcome the 35 USC 101 rejection above, the specification would still be enabling only for claims limited to the polypeptides comprising SEQ ID NO:4, pharmaceutical compositions and recombinant production thereof, because the specification does not reasonably provide enablement for a polypeptides comprising fragments of SEQ ID NO:4, proteins comprising amino acid sequences which are at least 95% identical to SEQ ID NO:4 or proteins comprising amino acids which are encoded by polynucleotides that hybridize to SEQ ID NO:3 or the complement thereof. This rejection is maintained for reasons of record. As applicant has not provided a utility for the instant galectin-9, or a molecular mechanism relating the protein to a particular disease state, one of skill in the art would not know how to make and use variants of the instant galectin-9 as one of skill in the art would not know how to

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modify the galectin-9 structure and retain functionality, as a functionality has not been disclosed, for the reasons of record given in paragraph 4 supra and the Office action of Paper No. 14.


Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
September 9, 2001


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